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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,168	09/25/2003	Gil M. Vardi	15305.0024USU1	2222
23552	7590	03/27/2008		
MERCHANT & GOULD PC			EXAMINER	
P.O. BOX 2903			HOUSTON, ELIZABETH	
MINNEAPOLIS, MN 55402-0903				
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,168

Applicant(s)

VARDI ET AL.

Examiner

ELIZABETH HOUSTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 13-17, 19-23 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 13-17, 19-23 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/08 has been entered.

Priority

2. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Drawings

3. The drawings were received on 11/19/07. These drawings are accepted.

Claim Rejections - 35 USC § 102

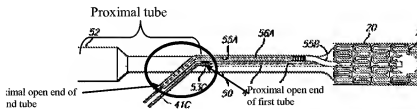
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13-17, 19 and 21-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson (EP 0 897 700).

5. Regarding claim 13, Wilson discloses a catheter with a proximal tube (where the proximal tube as shown below extends from the proximal end of the catheter to the guidewire opening) and a distal *portion* comprising a first tube (53A) with a proximal open end (53C) and a second tube (55A) with a proximal open end (for example 56C). There is a bond *portion* that connects that proximal tube with the distal *portion*. The bond portion has a three-way bond that couples the proximal tube portion to the proximal open end of the first tube and the proximal open end of the second tube.



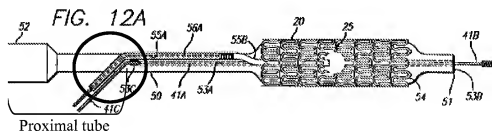
6. The first/main guidewire lumen/tube is attached to the branch/second lumen/tube external of the bond portion. The bond portion is located at a predetermined distance proximally from a proximal portion of the stent. The first and second guide wires exit at the bond portion.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson (EP 0 897 700).

8. Wilson discloses catheter system for positioning a stent at a vessel bifurcation substantially as claimed (see entire document). Specifically, Wilson discloses a catheter

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(Fig 12a-c) comprising a channel (53a) having a main guidewire lumen extending from a distal end (51) to a main exit port (53c) located at a first distance. There is a branch guidewire enclosure (55a) extending proximally from a side opening (25) of a stent (20) to a branch exit port (see for example 56c) located at a second distance. The branch guidewire enclosure is coupled to the channel adjacent (or near, close to) the branch exit port. The first and second distances of the exit ports are less than a distance from the proximal end to the distal end of the catheter and greater than a distance from the distal end of the catheter to the proximal end of the stent. The device has a balloon (54) and an inflation portion for inflating the balloon. The catheter comprises a bond portion (indicated by circle - see below) that connects the main exit port, the branch exit port and a proximal tube (where the proximal tube as shown below extends from the proximal end of the catheter to the guidewire opening).



9. Regarding the limitation "said first distance and said second distance being *substantially* equal"; the use of language such as "substantially" is terminology of a relative degree and merely requires that the prior art show the distances being close to equal.
10. Alternatively, should applicant disagree with examiner's interpretation of the terminology "substantially", examiner asserts that would be obvious to one having

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ordinary skill in the art at the time of the invention to vary the size of the branch guide wire tube (thereby changing the distance of the branch exit port) in order to produce a catheter with a more streamline profile for ease of delivery. Further, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5, 8, 17, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson.

13. Wilson discloses the claimed invention as stated above except for the dimensions locating the exit openings and the length of the guidewire and the attachment along the entire length of the second lumen/tube. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the size of the catheter and therefore the location of the exit ports depending on the size and location of the lumen in which it would be used. For instance catheter used on an infant would be significantly smaller than that used on a large adult. Additionally, a catheter that is being delivered to the aorta will be larger than one that is being delivered to the brain. Such a modification would have involved a mere change in the

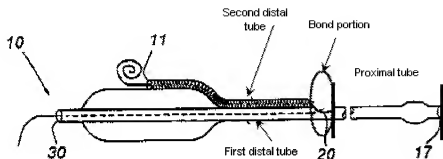
size of a component, and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

14. Regarding claim 17, it would be obvious to one having ordinary skill in the art at the time of the invention to vary the length of the branch guide wire tube in order to produce a catheter with a more streamline profile for ease of delivery. The modified catheter would result in one where the attachment of the first and second tube is along an entire length of the second tube.

15. Claims 21 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Ischinger (US 6,682,556).

16. Wilson discloses the invention above substantially as claimed except for the proximal end of the bond portion connecting to the proximal tube at the distal end of the proximal tube and the distal end of the bond portion connecting to the first and second distal tubes at their proximal open ends.

17. Ischinger teaches a similar stent delivery device having two guidewire tubes for delivery at a bifurcation. Ischinger teaches that the proximal open ends of the first distal tube and the second distal tube can be placed at different locations or at the same location (Compare figures 1a and 1b). The bond portion of the latter has a proximal end connected to the proximal tube at the distal end of the proximal tube and a distal end of connected to the first and second distal tubes at the proximal open ends of each tube (see below).



18. Both Wilson and Ischinger disclose similar inventions having a proximal tube and two distal tubes and a bond portion that connects the proximal openings of the distal tubes with the proximal tube. Ischinger discloses an equivalent species where the bond portion is specifically connected to the proximal tube and distal tubes as claimed. Because the two embodiments were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the vary the location of the proximal opening of the second distal tube, since substitution of one known element for another would have yielded predictable results.

Response to Arguments

19. Applicant's arguments filed 11/19/07 have been fully considered but they are not persuasive. Applicant argues that Wilson does not disclose that the branch guidewire opening is coupled to the channel at the branch exit port. However the term "at" is interpreted the same as the term "adjacent" in that the branch guidewire opening is coupled to the channel *near* the branch exit port.

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20. Applicant continues to argue that Wilson does not disclose a three way bond. However, the claim recites “three way bond *portion*”.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731